WHOLESALE DISTRIBUTOR REGISTRATION
FREQUENTLY ASKED QUESTIONS

What is a wholesale distributor?

A wholesale distributor is someone who is engaged in the wholesale distribution of prescription or over the counter drugs and devices in and into the state of Kansas, including but not limited to, manufacturers, repackagers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, co-licensees, exclusive distributors, third party logistics providers, chain pharmacy warehouses that conduct wholesale distributions, and wholesale drug warehouses, independent wholesale drug traders, and retail pharmacies.

What if I manufacture drugs but do not deliver them into Kansas and use a 3rd party to deliver the drugs. Do I need to be registered?

No. Only the entity that is actually shipping the drugs into Kansas needs to be registered with the Board of Pharmacy. It does not matter whether the ownership of the drugs have been transferred. All entities doing the actual shipping need to be registered in Kansas.

What is a drug in Kansas that would require some type of registration before it can be shipped into the state?

A drug is a product recognized in the official National Formulary, or the United States Pharmacopeia intended for the use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals, or is intended to affect the structure of any function of the body of man or other animals, or products used as a component in the above. Drugs are both prescription and over-the-counter and their intended use is achieved through chemical action or by being metabolized by the body. If you are unsure of whether your product is a drug you may contact the Board office and ask what type of registration you would need.

What if the product I distribute has been deemed a device by the FDA? Is it exempt in Kansas?

Yes, devices are excluded in Kansas.

What is a prescription-only drug?

A prescription drug means a drug, whether intended for use by man or animal, required by federal or state law to be dispensed only pursuant to a written or oral prescription order of a practitioner or is restricted to use by practitioner only. The

FDA says that a Prescription drug product means a specific strength or potency of a drug in final dosage form for which a human drug application has been approved and which may be dispensed only by prescription under section 503(b) of the FD&C Act, and, after October 1, 2002, is also on the list of products described in section 505(j)(7)(A) or is on a list created and maintained by the Secretary of products approved under human drug applications under section 351 of the Public Health Service Act. (Section 351 of the PHS Act provides the authority for regulating biological products. Biological products are regulated by the Center for Biologics Evaluation and Research.)

If the company is shipping or delivering a prescription-only drug what registrations are they required to have?

They are required to have a Distributor of Prescription Drug or Controlled Substances registration. The application can be found on the Board web site under the link for "Applications and Forms" and under the title "Distributor of Prescription Drugs or Controlled Substances Application".

What if I am only distributing over-the-counter drugs? Do I need a registration?

Yes. If you are only distributing over-the-counter drugs you would need to be registered as a "Non Prescription Wholesale Distributor." The link to the application is found under "Applications and Forms" and is under the title "Non Prescription Wholesale Distributor".

What if I deliver both prescription-only and over the counter (OTC) products? Do I need to have two registrations?

No. The Distributor of Prescription Drugs Registration covers every type of drug so you would only need to have the one registration.

Can a wholesale drug distributor deliver directly to the patient?

Only in certain circumstances. Generally, you must be delivering at wholesale to a business entity that sells, leases, dispenses, or administers the drugs. Patients are required to obtain their drugs and devices from a pharmacy, a retail dealer or a DME provider. The exceptions are if you are delivering dialysates, are a Veterinary wholesaler, or delivering oxygen.

What type of things do the inspectors look for during a pre-inspection of a wholesale distributor located in Kansas?

The inspectors will look at the cleanliness and maintenance of the location. They will check for ventilation, temperature control and security, dependant on what products are being maintained. They will look to make sure that the records are maintained at the location. They may look at the policy and procedure manual regarding handling recalls and will look at the business quarantine area. They will look for out dated product that can never be offered for sale or lease. If the business provides oxygen they must purchase it from a Board of Pharmacy and FDA registered business.

What if I close my business or move to a new location?

If you close your business you would need to return your registration certificate to the Board of Pharmacy upon closure. A move to a new location would require a new registration and a new fee. A location in Kansas would be subject to a pre-opening inspection.

What can I do to keep up with current Board of Pharmacy laws and regulations?

The Board web site at www.kansas.gov/pharmacy maintains proposed regulations and updated laws. You can also sign up for a quarterly board newsletter on the board web site.